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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KING PHARMACEUTICALS, INC. and MERIDIAN MEDICAL TECHNOLOGIES, INC., Plaintiffs, v. SANDOZ INC., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs King Pharmaceuticals, Inc. ("King Pharmaceuticals") and Meridian Medical Technologies, Inc. ("Meridian") (collectively, "Plaintiffs") bring this action for patent infringement against Defendant Sandoz Inc. ("Defendant" or "Sandoz"). Plaintiffs allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendant Sandoz's filing of Abbreviated New Drug Application ("ANDA") No. 090725 with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiff Meridian's highly successful EpiPen® Auto-Injector prior to the September 11, 2025 expiration of U.S. Patent No. 7,449,012 B2.

THE PARTIES

2. Plaintiff King Pharmaceuticals is a Tennessee corporation with its principal place of business at 501 Fifth Street, Bristol, Tennessee 37620. King Pharmaceuticals is in the business of developing, manufacturing, and bringing innovative medicines and technologies to market, primarily in specialty-driven markets including neuroscience and acute care medicines.

3. Plaintiff Meridian is a Delaware corporation with its principal place of business at 10240 Old Columbia Road, Columbia, Maryland 21046. Meridian is a wholly-owned subsidiary of King Pharmaceuticals.

4. Meridian is the holder of approved New Drug Application No. 019-430, and markets the product which has the proprietary name EpiPen® (epinephrine) Auto-Injector 0.3/0.15 mg ("EpiPen® Auto-Injector") pursuant to this NDA. On July 17, 2009, as required by the Federal Food, Drug, and Cosmetic Act ("FFDCA") and FDA regulations, Meridian submitted information concerning the '012 patent for listing in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." Meridian developed and manufactures the EpiPen® Auto-Injector, an easy-to-use, disposable drug delivery system featuring spring activation and a concealed needle. The EpiPen® Auto-Injector is sold

throughout the United States and worldwide.

5. Upon information and belief, Defendant Sandoz is a Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540, U.S.A. Upon information and belief, Sandoz develops and markets a wide range of generic drug products and regularly conducts business throughout the United States, including in the State of New Jersey.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This court has personal jurisdiction over Sandoz because, among other things, Sandoz's principal place of business is in New Jersey. By virtue of Sandoz's presence and regular and continuous business in the State of New Jersey, Sandoz has submitted itself to the personal jurisdiction of the courts in New Jersey.

8. This Court also has personal jurisdiction over the Defendant by virtue of the fact that, among other things, Sandoz has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which manufacture numerous drugs for sale and use throughout the United States, including this judicial district. This Court has personal jurisdiction over the Defendant for the additional reasons set for below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

BACKGROUND

10. The EpiPen® Auto-Injector is designed for assisted- or self-administration of epinephrine

in acute allergic emergencies (anaphylaxis), by providing a rapid, convenient dose of epinephrine for individuals needing protection from potentially fatal allergic reactions.

11. Meridian developed and manufactures the EpiPen® Auto-Injector pursuant to New Drug Application No. 019-430, which was approved by FDA.

12. United States Patent No. 7,449,012 B2 ("the '012 patent"), entitled "Automatic Injector" was duly and legally issued by the U.S. Patent and Trademark Office on November 11, 2008. The '012 patent, owned by Meridian, will expire on September 11, 2025. A copy of the '012 patent is attached hereto as Exhibit A.

13. The EpiPen® Auto-Injector is covered by one or more claims of the '012 patent, and as such, the '012 patent was listed in connection with the EpiPen® Auto-Injector in FDA's Orange Book.

14. Upon information and belief, Sandoz submitted ANDA No. 090725 under 21 U.S.C. § 355(j)(2) in order to obtain FDA approval to engage in the commercial manufacture, use, and/or sale of a generic version of the EpiPen® Auto-Injector prior to the expiration of Meridian's '012 patent.

15. By letter dated June 3, 2010, Sandoz notified Plaintiffs that Sandoz had submitted and FDA had received ANDA No. 090725 concerning Sandoz's proposed drug product, epinephrine injection 0.3mg/0.3 mL and 0.15/0.3 mL ("Sandoz's ANDA product"), as required by § 505(j)(2)(B)(i) and (ii) of the FFDCA. *See* 21 U.S.C. § 355(j)(2)(B)(i)–(ii).

16. Sandoz's June 3 letter also notified Plaintiffs that, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Sandoz filed with FDA a paragraph IV certification with respect to the '012 patent, alleging that the claims of the '012 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale, or offer for sale of Sandoz's ANDA product. *See* 21

U.S.C. § 355(j)(2)(A)(vii)(IV).

17. Sandoz's submission of ANDA No. 090725 seeking approval for the commercial manufacture, use, offer for sale, and/or sale of Sandoz's ANDA product before the expiration of the '012 patent constitutes an act of infringement of one or more claims of the '012 patent under 35 U.S.C. § 271(e)(2)(A).

18. Plaintiffs received Sandoz's June 3 letter on or about June 8, 2010.

19. In accordance with the contact information Sandoz provided in its June 3 letter, Plaintiffs contacted Mr. Stephen R. Auten, Esq. ("Mr. Auten") by email on June 11, 2010, in order to gain access to Sandoz's ANDA and to address the terms of Sandoz's Offer of Confidential Access ("OCA"). Sandoz did not reply to this correspondence.

20. Plaintiffs again contacted Mr. Auten by email on June 18, 2010, requesting access to Sandoz's ANDA. Again, Sandoz did not reply.

21. Plaintiffs contacted Mr. Auten a third time by email on June 25, 2010. Plaintiffs again requested immediate access to Sandoz's ANDA. Sandoz did not reply to this email.

22. On July 2, 2010, Plaintiffs sent Mr. Auten a letter via Federal Express, reiterating their request for Sandoz's ANDA and attaching a copy of all prior email correspondence. As confirmed by Federal Express, delivery of this letter to Sandoz occurred on July 6, 2010. To date, Sandoz has not responded to the July 2 letter.

23. To date, Sandoz has not replied to any one of Plaintiffs' several attempts to gain access to Sandoz's ANDA.

COUNT 1
INFRINGEMENT OF U.S. PATENT NO. 7,449,012 B2

24. Plaintiffs reallege and incorporate by reference paragraphs 1–23, above.

25. Meridian is the owner by assignment of the '012 patent and has the right to sue for

infringement thereof.

26. Upon information and belief, Sandoz's ANDA product, when offered for sale, sold, and/or imported, and then used as directed, would be used in a manner that would directly infringe one or more of the claims of the '012 patent.

27. Upon information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA product would infringe one or more claims of the '012 patent. *See* 35 U.S.C. § 271(a).

28. Upon information and belief, Sandoz intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA product, with its proposed labeling, immediately and imminently upon approval of ANDA No. 090725.

29. Upon information and belief, immediately upon approval of ANDA No.090725, Sandoz will infringe the '012 patent by making, using, offering to sell, selling, and/or importing Sandoz's ANDA product in the United States, and by actively inducing and contributing to others' direct infringement under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 090725 shall be no earlier than the expiration of the '012 patent.

30. Upon information and belief, the use of Sandoz's ANDA product constitutes a material part of at least one or more claims of the '012 patent; Sandoz knows that its product is especially made or adapted for use in a manner infringing at least one or more claims of the '012 patent; and Sandoz's ANDA product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

31. Upon information and belief, the offering to sell, sale, and/or importation of Sandoz's ANDA product would contributorily infringe one or more claims of the '012 patent.

32. Upon information and belief, Sandoz had knowledge of the ’012 patent and, by its promotional activities and package insert for Sandoz’s ANDA product, knows or should know that it will actively aid and abet another’s direct infringement of one or more claims of the ’012 patent.

33. Upon information and belief, the offering to sell, sale, and/or importation of Sandoz’s ANDA product would actively induce infringement of one or more claims of the ’012 patent.

34. Unless Sandoz is enjoined from infringing the ’012 patent, actively inducing infringement of the ’012 patent, and/or contributing to the infringement by others of the ’012 patent, Plaintiffs King Pharmaceuticals and Meridian will be substantially and irreparably harmed. Plaintiffs have no adequate remedy at law.

COUNT II
DECLARATORY JUDGMENT

35. Plaintiffs reallege and incorporate by reference paragraphs 1–34, above.

36. Upon information and belief, if ANDA No. 090725 is approved, Sandoz’s ANDA product will be distributed in the United States by Sandoz and its affiliates.

37. Upon information and belief, Defendant knows that patients will use Sandoz’s ANDA product in accordance with the labeling sought in ANDA No. 090725 and Defendant will therefore infringe one or more claims of the ’012 patent.

38. Upon information and belief, Defendant plans to begin marketing, selling, and offering to sell Sandoz’s ANDA product immediately after FDA approves ANDA No. 090725. Such conduct will constitute infringement of one or more claims of the ’012 patent under 35 U.S.C § 271.

39. Upon information and belief, Defendant’s infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Sandoz’s ANDA product complained of

herein will begin immediately after FDA approves ANDA No. 090725.

40. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy concerning liability for the infringement of the ’012 patent between Plaintiffs King Pharmaceuticals and Meridian and Defendant Sandoz.

41. Plaintiffs Meridian and King Pharmaceuticals will be substantially and irreparably harmed by Sandoz’s infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(1) a declaratory judgment that, under 35 U.S.C. § 271(e)(2)(A), Sandoz’s submission to FDA of ANDA No. 090725 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sandoz’s ANDA product before the expiration of the ’012 patent was an act of infringement of one or more claims of the ’012 patent;

(2) a declaratory judgment that Sandoz’s commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sandoz’s ANDA product would constitute infringement of one or more claims of the ’012 patent;

(3) an order that the effective day of any FDA approval of Sandoz’s ANDA product shall be no earlier than the expiration of the ’012 patent, in accordance with 35 U.S.C. § 271(e)(4)(A);

(4) a permanent injunction, enjoining Sandoz, its affiliates and subsidiaries, and all persons and entities acting in concert with Sandoz, from commercially manufacturing, using, offering for sale, or selling Sandoz’s ANDA product within the United States, or importing Sandoz’s ANDA product into the United States, until the expiration of the ’012 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(5) an award of damages or other relief if Sandoz engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, and/or importation of Sandoz's ANDA product, or any product that infringes one or more claims of the '012 patent, prior to the expiration of the '012 patent, in accordance with 35 U.S.C. § 271(e)(4)(C);

(6) a declaration that this is an exceptional case, and an award of attorneys' fees to Plaintiffs, in accordance with 35 U.S.C. § 285;

(7) an award to Plaintiffs of their costs and expenses in this action; and

(8) such further and additional relief as this Court deems just and proper.

Dated: July 14, 2010

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RULE 11.2 CERTIFICATION

I hereby certify that the matter in controversy is related to the following action pending before the Chief Judge Gregory M. Sleet in the U.S. District Court for the District of Delaware, captioned King Pharmaceuticals Inc. et al. v. Teva Parenteral Medicines Inc. et al., Civil Action No. 1:09-cv-00652-GMS

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RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the plaintiffs seek, *inter alia*, injunctive relief.

Dated: July 14, 2010

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